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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,272	07/24/2006	Rolf Berge	966917.00012	6396

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REED SMITH LLP
3110 FAIRVIEW PARK DRIVE
FALLS CHURCH, VA 22042

EXAMINER	
ARIANI, KADE	
ART UNIT	**PAPER NUMBER**
1651	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,272	BERGE, ROLF	
	Examiner	Art Unit	
	Kade Ariani	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 17-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 17-33 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed on 01/04/2006, has been received and entered.

Claims 1-16 have been canceled.

Claims 17-33 are pending in this application and were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention nor was the claimed subject matter described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant alleges that the instant method is a "method of preventing" and as the term "preventing" is an absolute term, the claims cannot be considered enabled for "a method of preventing". To enable "method of preventing " applicant would need to demonstrate to the skilled artisan that the agent would prevent any and all cases and causes of the claimed disorders and the specification has no such showing

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kristisson & Rasco (Critical Reviews in Food Science and Nutrition, 2000, Vol. 40, No.1, p. 43-81).

Claims 17-25 are drawn to a method of treating or preventing a disease comprising administering to an animal, a composition comprising an enzyme treated fish protein hydrolysate (FPH) material.

Kristisson & Rasco disclose administering to an animal and human, a composition comprising an enzyme treated fish protein hydrolysate (FPH) material (p.44, 1st column, 2nd paragraph).

Kristisson & Rasco do not disclose preventing fatty liver, hypercholesterolemia, and hyperhomocysteinemia. However, the composition being administered is fish protein hydrolysate (FPH) material and therefore has to have the claimed diseases preventing properties.

Therefore, Kristisson & Rasco clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. (Journal of Nutrition, 1992, vol. 122, p.1731-1737) in view of Kristisson & Rasco (Critical Reviews in Food Science and Nutrition, 2000, Vol. 40, No.1, p. 43-81) and further in view of Van Guldener & Stehouwer (Expert Opin. Pharmacother. 2001, Vol. 2, No. 9, p.1449-1460).

Claims 17-25 are drawn to a method of treating or preventing a disease comprising administering to an animal in need of such treatment, a pharmaceutical or nutritional composition comprising an enzyme treated fish protein hydrolysate (FPH) material, wherein the disease is fatty liver, hypercholesterolemia, hyperhomocysteinemia, the animal is human, an agricultural animal, a fish, nutritional composition is a food grade product.

Bergeron et al. teach a method comprising administering to an animal, a nutritional composition comprising fish protein (92.5 % protein). Bergeron et al. teach, "fish protein has been shown to be cholesterol-lowering when fed to rabbits but

hypercholesterolemic when included with a 1% corn oil diet, and "current data indicates that fish protein can produce variable effects on serum total cholesterol concentrations, depending in part on the amount and origin of the dietary lipid with which it is combined" (p. 1731 column 1 lines 6-8 and 10-12 and column 2, lines 1-2, also page 1733, Table 1.).

Bergeron et al. teach feeding fish protein to rabbits has consistently been shown to increase HDL cholesterol, compared with casein, and soybean protein, regardless of the fat source and content of the purified diet (p.1731, column 2, lines 9-15).

Bergeron et al. does not teach an enzyme treated fish protein hydrolysate (FPH) material. However, Kristisson & Rasco teach an enzyme treated fish protein hydrolysate material, the use of FPH as a functional food ingredient, and conversion of low value fish materials into more valuable and palatable products (p. 44, column 1, p. 53-54, p. 74-75).

Kristisson & Rasco teach, enzymatic hydrolysis of fish protein has been employed as an alternative approach for converting underutilized fish biomass into edible protein products, using suitable enzyme/substrate ratios and reaction times, permits the production of hydrolysate with different molecular structures and different functional properties that could find applications in various food formulations, and to obtain fish protein hydrolysate of a lipid content not exceeding 0.5% by weight as advised by the protein Advisory groups of FAO for a fish protein hydrolysate suitable for human consumption (p. 54 column 1, 2nd paragraph, p. 55 column 1, lines 5-9).

Moreover, at the time the invention was made, it was very well known in the art that, elevation of lipids (cholesterol) in the bloodstream was associated with the development of atherosclerosis and cardiovascular diseases. Also, at the time the invention was made it was well known that elevated homocysteine levels in blood caused atherosclerotic disease (Van Guldener & Stehouwer, p.1449 -1450).

Therefore, it would have been obvious to one of ordinary skill in the art to use enzyme treated fish protein hydrolysate disclosed in Kristisson & Rasco in the method of Bergeron et al. to achieve the claimed invention. The motivation would be to combine the cholesterol lowering effect of fish protein diet as taught by Bergeron et al, with the ability to obtain fish protein hydrolysate with low lipid content, and therefore to lower the risk of cardiovascular diseases.

Claims 26-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielson (US 2002/0182290 A1) in view of Kristisson & Rasco (Critical Reviews in Food Science and Nutrition, 2000, Vol. 40, No.1, p. 43-81) and further in view of Sharma et al. (Bioresource Technology, 2002, Vol. 85, p.327-329) and further in view of Pena-Ramos et al. (Journal of Food Science, 2002, Vol. 67, No. 8, p.2952-2956).

Claims 26-33 are drawn to a method of producing an enzyme treated fish protein hydrolysate (FPH), comprising the steps of, hydrolyzing fish flesh remnants with a protease enzyme at a pH in the range of 5.0-8.0 and at a temperature in the range of 40-70°C to yield a hydrolysate, raising the temperature to about 90-99°C, removing an insoluble fraction by decanting and filtering, separating the remaining mixture in a three phase separator into an oil fraction, an emulsion fraction, and aqueous fraction, and

isolating and filtering the aqueous fraction through an ultra-membrane with a nominal molecular weight limit of 100,000, spray drying the hydrolysate, FPH contains proteins in the range 70-90%, fish flesh remnants on salmon bone frames after filleting, a Bacillus protease enzyme complex, pH in the range of 6.0-7.0, a temperature in the range of 50-60°C.

Nielson teaches a method of producing an enzyme treated fish protein hydrolysate, comprising the steps of, hydrolyzing fish flesh remnants with a protease enzyme at a temperature in the range of 40-70°C to yield a hydrolysate, raising the temperature to about 90-99°C, *Bacillus* protease enzyme complex (Protamax), removing an insoluble fraction by decanting and filtering (the material was sieved), fish flesh remnants on salmon bone frames after filleting, an oil fraction, an emulsion fraction, and aqueous fraction, drying (page 3 and 4, 0037, 0038).

Nielson further teaches a nutritional composition comprising an enzyme treated fish protein hydrolysate material, human, an agricultural animal, fish, and a food grade product (page 3, 0030-0032).

Nielson teaches the protease treatment is conducted at any condition found suitable for the protease and to provide a desired separation of fish meat from the fish bones (page 3, 0029). Also, at the time the invention was it was well known in the art that, *Bacillus* protease complex (Protamex) optimum pH is 7.0 (Pena-Ramos et al., p.2952, column 2, Enzymatic hydrolysis, line 18).

Nielson does not teach the claimed amino acid content of the PFH material, proteins in the range 70-90%, three-phase separation, an ultra-membrane, spray drying.

However, since the enzyme (Bacillus protease complex), the substrate (salmon bone frames after filleting), and incubation temperature used in the method of Nielson appears to be the same as the enzyme, the substrate, and the incubation temperature in the claimed invention, therefore, one can assume that the fish protein hydrolysate product obtained after the enzyme treatment of Nielson, must have amino acid content same as the FPH of the claimed invention.

Moreover, Kristisson & Rasco teach, a method of producing an enzyme treated fish protein hydrolysate material, proteins in the range 70-90% (p.57, column 1 lines 21-22), phase separation, ultrafiltration, and spray drying the hydrolysate (p. 63, column 2, lines 1-11, and figure 7 p. 64, column 1 2nd paragraph).

Furthermore, Sharma et al. teaches three-phase partitioning (TPP) has been used for processing proteins and further teaches using TPP process it is possible to simultaneously separate oil and protein (see Abstract and Introduction, and p.328, column 2, 2nd paragraph).

Therefore, it would have been obvious to one of ordinary skill in the art to use three-phase partitioning as taught by Sharma et al. in the method of producing enzyme treated fish protein hydrolysate as taught by Nielson and/or Kristisson & Rasco, to achieve the predictable result of producing and simultaneously separating fish protein hydrolysate and lipid and to obtain simpler extraction design.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

Leon B. Lankford Jr.
Primary Examiner
Art Unit 1651